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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,701	12/06/2005	Catherine Abbadie	21156YP	1960
210 7590 09/18/2007 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			EXAMINER PAGONAKIS, ANNA	
			ART UNIT 1609	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,701

Applicant(s)

ABBADIE ET AL.

Examiner

Anna Pagonakis

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Applicants' election filed on 07/23/2007 has been received and entered into the application. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 2-4 have been amended, and no claims have been cancelled or added. Claims 1-4 are presently under examination and are the subject of this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the designation "CCR-2 antagonist" renders the claims indefinite as the recitation is too vague. "CCR-2" is a simple acronym/abbreviation that has many different meanings in the art and thus the inclusion thereof is confusion and the claims indefinite. Applicant could simply spell out the full name of the receptor in at least the first occurrence to obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of neuropathic pain, does not reasonably provide enablement for the prevention of neuropathic pain. As stated in the instant disclosure, “treating” (see instant claim 1) includes the prevention or prophylactic therapy of neuropathic pain (Specification page 270-271). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and

8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1) and 2) The claimed invention is directed to a method for treating neuropathic pain by administering to a patient in need of such treatment a therapeutically effective amount of CCR-2 antagonist.

3) There is known unpredictability in the art when engaging in the treatment of patients experiencing neuropathic pain. Although there are a number of efficacious therapies that can be used for the treatment of patients with neuropathic pain, the use of any one or more of these therapies does not necessarily guarantee that the prevention of such pain will be achieved. Barker et al. (*Principles of Ambulatory Medicine*, Fourth Ed; 1995: 1255) acknowledges that the "pain associated with a condition such as neuropathic pain, it is recognized that prevention of further symptoms or eliminating the possibility of recurrent pain does not invariably result. In addition, certain therapies, such as opioids, may induce other adverse events that complicate the treatment of neuropathic pain, such as narcotic addiction (see Barker et al., p.1255). As a result, prevention of pain in response to such conventional therapies is unpredictable and varies by patient. Specifically, the outcome of treatment with the proposed therapy described in the instant

application cannot guarantee complete prevention of further pain or painful symptoms associated with the condition.

4) Applicant has merely disclosed that by administering the claimed agent in a rat or mouse with neuropathic pain, one may treat or prevent neuropathic pain in the animal. Based on the discussion in Section 3 above, however, such disclosure clearly is not adequate direction or guidance as to how the proposed CCR-2 antagonist can be employed to accomplish the prevention of neuropathic pain in a predictable manner.

5) The specification provides data demonstrating the use of the elected compound known to be a CCR-2 antagonist is effective in treating neuropathic pain in rat/mice. That data is not, however, commensurate in scope with the claimed subject matter. The present claims encompass *preventing* neuropathic pain, while Applicant's data merely establishes that the compounds have activity in treating pain associated with neuropathy.

6) The burden of enabling the prevention of pain associated with neuropathy is much greater than that of enabling the treatment of the same condition. Since the present specification would not enable the skilled artisan to prevent neuropathic pain, a clear burden of undue experimentation would be placed upon the skilled artisan in order to practice this aspect of the invention.

7) Conventional therapies, such as conventional analgesics (such as aspirin) or narcotics are used to treat the pain associated with neuropathy are well known in the art as potentially efficacious treatments for this condition. The use of these conventional therapies in treating a specific patient population, that is, those patients known to be experiencing this disorder, was well defined in the art and allows for predominantly predictable and invariable results, in that it was well known that these therapies would reduce the level of pain associated with this condition. However, it is established above in Section 3 that it is more difficult to prevent the occurrence or recurrence of pain or the painful symptoms associated with neuropathy than it is to simply attenuate the level of pain associated with the condition.

8) In view of the discussion of each of the preceding seven factors, the level of skill in this art is high and is at least that of a medical doctor with several years of experience in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Jiao et al (US PGPub 2005/0101628A1).

Jiao et al. teaches the elected compound in claim 2 as a modulator of chemokine activity (specification, page 52, example 23). The disclosure also states that “inhibitors of chemokine receptor function may also be useful in the treatment and prevention of ... neuropathic pain” (specification page 8, column 2, line 8).

Furthermore, the reference teaches that the elected compound can be administered with a pain reliever for treatment. Though the reference does not specifically disclose the administration of the pain reliever for “neuropathic” pain but rather for inflammation, Mayer et al. (US Patent 5,502,058) teaches that “neuropathic pain is thought to be a consequence of damage to peripheral nerve or to regions of the central nervous system. However, abnormal functioning of pain-related regions of the nervous system also occur with chronic inflammatory conditions such as certain types of arthritis and metabolic disorders such as diabetes as well as with acute inflammatory conditions. Thus, many types of chronic pains that are related to inflammation as well as acute pains that are related to inflammation can be considered to be neuropathic pains.” (specification column 1, paragraph 4).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application

Art Unit: 1609

claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-27 of U.S. PGPub 2005/0101628A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims read on the claims of a patent already granted to the assignee.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pagonakis whose telephone number is 571-270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1609

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

 9/15/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER